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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,683	05/04/2001	Rebanta Bandyopadhyay	3479	8928

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
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[REDACTED] EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)
	09/849,683	BANDYOPADHYAY ET AL.
	Examiner Dwayne C Jones	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-39 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-39 are pending.
2. Claims 1-39 are rejected.

Response to Arguments

3. Applicants' arguments filed March 17, 2003 have been fully considered but they are not persuasive. Applicants make the following arguments: First, applicants allege that not all COX-2 inhibitors are interchangeable and that Masferrer, J.L. et al. do not give any indication to the skilled artisan to choose which inhibitors are likely to be successful. Next, applicants purport that different ocular inflammatory disorders have different treatments and accordingly it cannot be assumed that COX-2 inhibitors can be used interchangeably to treat ocular inflammation without regard to its cause, and so Miyake et al. should be withdrawn.

4. First, applicants allege that not all COX-2 inhibitors are interchangeable and that Masferrer, J.L. et al. do not give any indication to the skilled artisan to choose which inhibitors are likely to be successful and thus, a *prima facie* case of obviousness has not been made. This argument is only found persuasive for the claims which specify particular COX-2 inhibitors, accordingly claims 1, 2, 12, 14-16, 19-21 are again rejected over the prior art reference of Masferrer, J.L. et al. Specifically, Masferrer, J.L. et al. provide motivation to develop and or use selective nonsteroidal COX-2 inhibitors for the treatment of inflammatory diseases, including ocular inflammatory conditions, (see

abstract). For these reasons, the skilled artisan is presented with the necessary motivation and direction to treat the instantly claimed ocular inflammatory conditions with COX-2 inhibitors, as taught by Masferrer, J.L. et al.

5. Next, applicants purport that different ocular inflammatory disorders have different treatments and accordingly it cannot be assumed that COX-2 inhibitors can be used interchangeably to treat ocular inflammation without regard to its cause, and so the rejection in view of Miyake et al. should be withdrawn. This allegation is not found persuasive because Miyake et al. specifically teach of the administration of COX-2 inhibitors for the treatment of ocular disorders. It is well within the purview of the skilled artisan to utilize a COX-2 inhibiting compound for the treatment of ocular disorders because Miyake et al. list three examples of COX-2 inhibitors for the treatment of ocular disorders that are mediated by the COX-2 enzyme, (see abstract). The information provided by Miyake et al. instills the necessary motivation to the skilled artisan to simply select other inhibiting compounds of the COX-2 enzyme for the treatment of ocular disorders that are mediated by the COX-2 enzyme.

Information Disclosure Statement

6. The information disclosure statement filed May 21, 2002 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in

the English language. It has been placed in the application file, but the information referred to therein has not been considered. This is in response to those references, which did not have an English language equivalent, abstract or a concise explanation of the relevance.

7. The information disclosure statement filed May 21, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. In particular, this information disclosure statement did provide copies of the nonpatent literature.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear and confusing language to use the phrase, "the source of the COX-2 inhibitor comprises a COX-2 inhibitor." Here, applicants are defining the variable of a COX-2 inhibitor for the very same variable of a COX-2 inhibitor.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1, 2, 12, 14-16, 19-21 are again rejected under 35 U.S.C. 103(a) as being unpatentable over MASFERRER J. L. et al. Accordingly, this rejection is repeated. MASFERRER J. L. et al. disclose that the inhibition of the COX-2 enzyme will lead to the therapeutically desired inhibition of the generation of pro-inflammatory prostaglandins. MASFERRER J. L. et al. also provide motivation to develop and or use selective nonsteroidal COX-2 inhibitors for the treatment of inflammatory diseases, including ocular inflammatory conditions, (see abstract). Although the prior art reference of MASFERRER J.L. et al. do not recite specific COX-2 inhibitors, the skilled artisan is provided with the motivation to develop and or use selective nonsteroidal COX-2 inhibitors to treat ocular inflammatory conditions. Accordingly, one having ordinary skill

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in the art would have been motivated to use the teachings of Masferrer J. L. et al. to use COX-2 inhibitors to treat ocular inflammatory conditions.

13. The rejection of claims 1-39 under 35 U.S.C. 103(a) as being unpatentable over Miyake et al. of WO 9959634 is maintained for both the above-stated and reasons of record. Miyake et al. teach of the using selective COX-2 inhibitors to treat ocular inflammation. Although Miyake et al. does not recite specific causes of the inflammation, Miyake et al. do in fact teach the skilled artisan of a method of treating inflammation in the eye regardless of its causes. Clearly, the skilled artisan would have been motivated to utilize the selective COX-2 inhibitors of Miyake et al. to treat ocular inflammation without regard to its cause. The fact remains that the generation of prostaglandins is prevented with the administration of COX-2 inhibitors. For this reason, a variety of diseases and or conditions related to ocular inflammation could be treated with the compounds, which inhibit the generation of proinflammatory prostaglandins, such as with the administration of COX-2 inhibitors.

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake et al. of WO 9959634 is maintained for both the above-stated and reasons of record. Miyake et al. teach of the using selective COX-2 inhibitors to treat ocular inflammation. Although Miyake et al. do not recite specific rates of the residence time of the active agent, it is well within the purview of the skilled artisan to determine optimum therapeutic indexes of dosage and modes and methods of administration. Accordingly, the skilled artisan would have been motivated to determine optimum amounts as well as modes and methods of administration to get the maximum effect of the drug.

Obviousness-type Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

16. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

17. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 40 of copending Application No. 09/904,098. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to the treatment of COX-2 mediated disorders of the eye with the administration of a selective COX-2 inhibitor.

19. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-
1235.

Marianne C. Jones
MARSHALL & SIEGEL
DARLENE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
July 19, 2003